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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,327	02/24/2004	Paul J. Sheskey	63633	9686

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Intellectual Property Section
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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,327	SHESKEY ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

To summarize the election of record, applicant elected Group I drawn to processes for dispersing fluids in a mass of solid particles.

MAINTAINED REJECTIONS

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 21 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,070,828 (hereafter patent '828') in view of Rudnic et al. (see below for citation) Although the

conflicting claims are not identical, they are not patentably distinct from each other because both teach a method where particles are agglomerated by being contacted with foam and then mixed. While the particle size recited by patent '828 is 1 mm to 25 mm and that of the instant claim is less than 1000 microns, routine experimentation by one of ordinary skill in the art based upon the teachings of patent '828 would render this limitation obvious. Patent '828 teaches cellulose esters and poly(vinylpyrrolidone) as the polymer included in the foam which are both known binders in the pharmaceutical art (see Rudnic et al. claim 8) and meet the limitation of the instantly claimed binder. Therefore claim 21 is obvious over claims 1-2 of U.S. Patent No. 7,070,828.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and

analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (previously cited) in view of Lopez (previously cited), and as evidenced by Rudnic et al. (previously cited).

Parikh et al. teach the coating of drug containing particle cores that are 80 to 300 micrometers in size (see paragraph 34; instant claims 21 and 24-25). Parikh et al. go on to teach both a taste masking and texture masking coating that are utilized in the invention (see paragraphs 20-21 and 35). This coating is also taught to cover the entire surface of the core (see paragraphs 32 and 35). An embodiment of a texture masking composition teaches an aqueous solvent in the form of ethanol and water that constitutes 90 wt% (as calculated by the examiner) of the coating preparation and also includes hydroxypropylmethylcellulose (see example 2). Rudnic et al. teach that hydroxypropylmethylcellulose was a known pharmaceutical binder (see claim 8; instant claim 21). The coating process is taught to occur in a fluidized bed or rotary coater (see

paragraph 43). The resulting particles are a granular material. After production of these coated particles, Parikh et al. teach the production of larger granules (agglomeration) (see paragraph 56; instant claims 21). Thus at the end of the processing steps of Parikh et al. agglomerated particles are the result. Although Parikh et al. teach that several methods can be used to coat the particle cores, they do not teach coating by application of a foam (see paragraphs 43 and 52).

Lopez teaches a process of coating pharmaceutical solid forms (see column 1 lines 6-8). Lopez teaches that the process of coating solid forms by conventional means of dipping, pouring, or spraying often leads to unevenness in the coating layer (see column 1 lines 11-12 and 15-20). In addition, Lopez teaches that spray coating a liquid typically requires high pressures to appropriately atomize the coating medium and poses several challenges to uniform coating (see column 1 lines 46-75). The process taught by Lopez to circumvent the challenges of standard spray coating is amenable to nearly any type of coating medium and results in even and uniform coating, as well as shortened processing times (see column 2 lines 65-66 and 73-75). Lopez teaches the method of introducing air into a coating composition to produce foam that is then sprayed onto the pharmaceutical solids (see example and column 3 line 72-column 4 line 9; instant claims 21 and 23).

The complete coverage of the drug particles is taught by Parikh et al., thus one of ordinary skill in the art at the time the invention was made would have found it obvious to modify their invention by using the foam coating technique of Lopez to help ensure that complete and uniform coverage of the particles could be achieved. Based upon the recitation of instant claim 21, mixing of the foam components into the particles and

agglomeration of the particles yields agglomeration of the solid particles; therefore this limitation is met by the foam coating method of Parikh et al. in view of Lopez. Therefore claims 21 and 23-26 are obvious over Parikh et al. in view of Lopez and as evidenced by Rudnic et al.

Claims 21-22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardie-Muncy et al. (previously cited) in view of Richardson et al. (previously cited)

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by foaming the a coating medium then applying the foam to the particles so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11). In particular, they teach that a binding agent is included at 0.1 to 20% in water to make up the foam composition (see column 2 lines 33-35; instant claim 26). Further, Hardie-Muncy et al. teach that their process forms a foam that is then mixed with the particles to form agglomerates (see column 2 lines 46-57; instant claim 22). Hardie-Muncy et al. do not explicitly teach that the particles contain therapeutic or recite their size.

Richardson et al. teach hygroscopic (moisture sensitive) bioactive (therapeutic) components (see column 1 lines 7-11). These components are taught to be less than 1000 microns in diameter (see (column 8 lines 35-41; instant claim 21).

Since some bioactive particles are known to be sized less than 1000 microns and also be moisture sensitive, based on Richardson et al., it would have been obvious to one of ordinary skill in the art to use such particles in the process taught by Hardie-Muncy et al. to protect them from undesired moisture and help them retain their desired

structure and function. Therefore claims 21-22 and 26 are obvious over Hardie-Muncy et al. in view of Richardson et al.

NEW REJECTIONS

Double Patenting

Claim 21 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-9 of U.S. Patent No. 7,011,702 (hereafter patent '702) in view of Rudnic et al. and Baichwal et al. (US Patent No. 5,773,025) Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a method where particles are agglomerated by being contacted with foam and then mixed. While the particle size and presence of a therapeutic are not recited by the claims of patent '702, agglomerated particles containing a medicament are taught by Baichwal et al. (see claim 1). In addition, the particles utilize in these agglomerates are taught to be 10 μm or less (see column 11 lines 28-48). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the particles of Baichwal et al. in the method of patent '702 since both envisioned the production of an agglomerated final product. Patent '702 teaches cellulose esters as the polymer included in the foam which is a known binder in the pharmaceutical art (see Rudnic et al. claim 8) and meet the limitation of the instantly claimed binder. Therefore claim 21 is obvious over claims 8-9 of U.S. Patent No. 7,011,702.

Claim Rejections - 35 USC § 103

Claims 21-22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardie-Muncy et al. as evidenced by the Parsley reference (www.hort.purdue.edu/newcrop/med-aro-factsheets/parsley.html; 1997) and the Particle Size reference (Particle Size-US Sieve Series and Tyler Mesh Size Equivalents www.azom.com/details.asp?ArticleID=1417; 2002).

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by foaming a coating medium then applying the foam to the particles so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11; instant claim 21). In one example, a water based air foam is produced utilizing gelatin as a binding agent (binder) in water and combined, without atomization, with a collection of bread particles (see column 2 lines 28-33 and example 1; instant claim 22). One subset of these particles (small bread particles) is taught to pass through a 14 US sieve size and be retained on a 50 US sieve size. The Particle Size reference teaches that a 14 US sieve size has openings that are 1.41mm in diameter while a 50 US sieve size has openings that are 297 μm in diameter. Thus this subset of particles must be between 297 and 1410 μm. The binding agent is included at 6.2% in the foam (as calculated by the examiner – see instant claim 26). In addition, parsley is included as a particulate ingredient in the agglomerate preparation. The Parsley reference teaches that this plant is known to have medicinal effects (e.g. therapeutic agent) (see paragraph 7; instant claim 21). The selection of any order of adding ingredients is prime facie obvious in the absence of new or unexpected results (see MPEP2144.04 IVc). Therefore the addition the particles on top of the foam or vice versa is obvious from the

teachings of Hardie-Muncy et al. since no evidence is provided by the instant application of any unexpected result from one particular order of addition (see instant claims 23 and 27). Also, it would have been obvious to one of ordinary skill in the art to include a set of particles whose average size was less than 1000 μm, 750 μm or 500 μm as feed material for the agglomerates as a matter of routine experimentation given that the lower end of the acceptable size range for the small bread particles is range 297 μm (see instant claims 21 and 24-25). Therefore claims 21-27 are obvious over Hardie-Muncy et al. as evidenced by the Parsley reference and the Particle Size reference.

Response to Arguments

Applicant's arguments and declaration filed November 30, 2009 have been fully considered but they are not persuasive.

Regarding declaration made under 37 CFR 1.132 and rejection under 35 USC 103(a):

While the insights provided by Dr. Kibbe are appreciated, they do not negate the teachings of Parikh et al. that recite the steps claimed in the instant application. Parikh et al. is concerned with the preparation of solid dosage forms that includes both the coating of particles and their granulation. Therefore there would have been good reason for one of ordinary skill in the art to look to other references concerned with coating technologies as well as granulation technologies to supplement the teachings of Parikh et al. "The reason or motivation to modify the reference may often suggest what the

inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)" (see MPEP 2144IV). Thus the prior art need not have the same motivation as applicants for performing the instantly claimed steps in order to still render them obvious. Also, the instant claims are drafted with open claim language, allowing the presence of intervening steps before the final product is reached. As Dr. Kibbe notes, granulation in this context refers to adhering numbers of particles together to make a granulate and Parikh et al. explicitly teach granulation of their particles to form them into tablets (see paragraphs 55 and 56). Therefore they teach the formation of agglomerated particles. In light of the supplementary teaches of Lopez about coating via an aqueous air foam and the motivation provided by Parikh et al. to uniformly coat their particles, all the claimed steps are recited and the claimed agglomerated, therapeutic containing end result is obtained; thereby meeting the claim limitations. In addition Dr. Kibbe discusses attributes of the final product that are not supported by any data or evidence which are also not persuasive.

All the claims do not exclude atomization of the foam during application process. Thus only the rejections of claims that require this limitation must teach a process without spraying the foam. Hardie-Muncy et al. which was cited previously and is again cited in the current rejections, presents just a teaching where a set of particles are agglomerated by combining them with binder containing, water-based air foam wherein the foam is not atomized.

Since applicants have not provided any evidence that applying foam onto particles as opposed to applying particles onto foam yields a new and unexpectedly different result, the prior art can teach one of the orderings for the addition of ingredients and render the other obvious (see MPEP2144.04 IVc).

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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/Caralynne Helm/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615